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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/067,620 | 02/04/2002 | Bob B. Buchanan | 416272003400 | 5250 |
| 20872 | 7590 | 03/03/2005 | EXAMINER | |
| MORRISON & FOERSTER LLP 425 MARKET STREET SAN FRANCISCO, CA 94105-2482 | | | NOLAN, PATRICK J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | |

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,620

Applicant(s)

BUCHANAN ET AL.

Examiner

Patrick J. Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Claims 1-16 are pending.

2. In an effort to practice compact prosecution. A supplemental office action is set forth below. The previous office action mailed 2-10-05 is vacated. However, the PTO-1449 documents will not be resent.

3. Applicant's election with traverse of Group I, claims 1-3 and 8-12 in the reply filed on 11-23-04 is acknowledged. The traversal is on the ground(s) that the Examiner has not demonstrated an undue burden would be imposed upon searching both groups, especially in light of the fact they are classified in the same class/subclass. This is not found persuasive because a search for product claim requires no recitation of steps as does a method claim and since a prior art search for a disclosed product does not necessarily result in a prior art reference disclosing the use of said product as recited in the claims it makes the requirement of doing two searches unduly burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-7 and 13-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11-23-04.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 8-12 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Del Val et al.(Reference 6 on the IDS submitted 2/3/03).

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Del Val et al., teaches the isolated 30 kDa protein from ragweed that is applicant's disclosed protein from which they generated tryptic fragments that resulted in the instantly recited SEQ ID Nos 1-11. Del Val et al., teaches the administration of said protein to dogs, thereby meeting the limitation of a composition comprising a protein. Since the claims are open in the recitation of comprising and each SEQ ID No is a fragment of the 30 kDa protein, the prior art teaches a protein comprising SEQ ID Nos 1-11 or an antigenic fragment comprising SEQ ID Nos 1-11.

It is noted the reference has a publication date of February 2001, and the instantly filed case has an effective filing date of February 4, 2002. Upon a review of the provisional application only 5 of the sequences were disclosed. So the date of the instantly filed claims is 2-4-2002.

However, it is customary at scientific meetings for abstract books to be available prior to the meeting or at the very least on the first day of the meeting. It is incumbent upon applicant since they have common inventors with the publication to establish when the abstract meeting book was made publicly available so the appropriate statute can be applied.

The prior art teachings anticipate the claimed invention.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,500,347.

The '347 patent teaches diagnostic compositions of CK20 or its fragments, of which SEQ ID NO. 21 is 100% identical to applicant claimed SEQ ID NO.9 in positions 16-21 (see columns 1-4 in particular). Since the claims read upon compositions of proteins comprising SEQ ID NO. 9, the claimed invention is anticipated.

The prior art teachings anticipate the claimed invention.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of claims 1 or 8 reads upon any protein or polypeptide that comprises SEQ ID Nos 1-11. Applicant has described one protein, a 30kDa protein isolated from ragweed that provides written description for base claims 1 and 8. There is no disclosure of what additional amino acid sequences are encompassed by the proteins of claims 1-3 or the fragments of claims 8-12. Therefore, the disclosure of one species does not give adequate written description of a genus of thousands or even possibly millions of proteins or polypeptides encompassed by claims 1 or 8.

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1-3 and 8-12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2-4, 16-18 and 22-24 of copending Application No. 10/067,484. This

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is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Both sets of claims are drawn to either compositions of proteins or fragments comprising the same exact SEQ ID NOS., or in the case of claims 16-18, the recited protein is made up of SEQ ID NOS. 1-11, as such they are of the same exact scope.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-3 and 8-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 14-18, 22-24, 32-35 of copending Application No. 10/067,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because each sets of claims are drawn to the same protein or peptides thereof. The instant rejection is based partly upon a different use of the compositions, which potentially makes them obvious. Furthermore, the protein of claim 1 and the kits of claims 32-35 in the '484 application make the diagnostic composition of the instantly recited claims obvious since the diagnosis of allergies recited in claims 1-3 in the instant application requires using kits and the isolated protein of the '484 application..

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. It is noted reference 3 on the IDS submitted 2-3-03 was considered but it was crossed out since pending US applications are not appropriate for publishing of the first page of a US Patent.

13. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

February 27, 2005